Public Copy

July 18, 2008

RECSAMO

08 JUL 22 AM 6: 02

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20004



Dear 8(e) Coordinator:



8EHQ-07-16913 Fluorinated Aliphatic Alcohol

This letter is to inform you of the preliminary results of a recently conducted developmental toxicity study in rats with the above referenced test substance.

Groups of 22 time-mated rats were administered formulations of the test substance on days 6 through 20 of gestation at dose levels of 0, 5, 25, 125, or 250 mg/kg/day. Doses were formulated in 0.5% aqueous methylcellulose and administered at a dose volume of 5 ml/kg. Dose formulations were determined to be homogeneous, stable under the conditions of use, and at targeted concentrations. During the in-life period, data collection included body weights, food consumption, and clinical observations. On day 21 of gestation, dams were euthanized and examined grossly. Gravid uterine weight was recorded and the uterine contents described and removed. Corpora lutea, implantation sites, and resorptions were counted for each litter. Live fetuses were individually identified and weighed. Fetuses were examined for external, visceral, and skeletal alterations.

Maternal and developmental toxicity were observed at 125 and 250 mg/kg/day. There was a reduction in cumulative weight change (GD 6-21) of 9 and 24% relative to controls at 125 and 250 mg/kg/day, respectively. Cumulative change calculated using maternal body weight adjusted for the weight of the products of conception was 21 and 50% lower at the same respective levels. Cumulative food consumption was reduced 8 and 12% relative to controls at 125 and 250 mg/kg/day. A slight increase in stained and/or wet fur was observed at 250 mg/kg/day. Test substance-related increases in skeletal variations (ossification delays in the skull and rib alterations) were noted at 125 and 250 mg/kg/day. At 250 mg/kg/day, there was a slight elevation in the incidence of pelvic bone ossification. At 125 and 250 mg/kg/day, there was no maternal mortality nor were there any test substance-related maternal gross observations. Likewise, at 125 and 250 mg/kg/day, there was no effect on fetal weight or litter sex ratio and there were no effects on the incidences of fetal resorptions or malformations (terata).

There were no effects on the dams or fetuses at 5 and 25 mg/kg/day.

Sincerely,

Company Sanitized